Prominence of active ingredients on medicine labels

Stated Objective(s)

The consultation paper states that the objective of the Review is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issue:

- information about the active ingredient(s) contained in the medicine is not always easy to find

Consumer risk(s) identified in the consultation paper

In relation to prescription medicines, the consultation paper indicates that: *"it is important to know the active ingredient so that the consumer avoids taking multiple doses of the same active ingredient".*

In relation to over-the-counter medicines, the consultation paper indicates that: *"it is common for several products with different brand names to include the same active ingredient" and that "a consumer who takes several of these products at the same time may receive an overdose of the active ingredient".*

The consultation paper singles out paracetamol and ibuprofen for specific attention, suggesting that an additional warning statement be included on the front of pack to address the issue of "accidental overdose".

Summary of ASMI Position

- The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements.
- The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers. Solutions for prescription medicines labels are not appropriate for non-prescription medicines labels.
- Consistent with a risk-based approach a distinction should be drawn between the different non-prescription medicines categories. We do not support a blanket approach to be applied to all non-prescription medicines.
- ASMI acknowledges the importance of consumers being able to readily identify product ingredients on the label and the risks associated with taking more than one product containing the same ingredient(s).
- ASMI believes that this could be achieved by giving <u>due</u> prominence to ingredient names. The notions of "greater" and "due" prominence are raised in the CHF paper (provided at Appendix 5[1]).
- Only one prominence option was put forward in the consultation paper; that of "equal prominence". ASMI does not support this proposal as there are alternative options possible which could effectively address the issue, ranging between "equal size" and the current situation. Our chief concerns are the potential detrimental impact on brand recognition, which is a vital element in consumer product selection and the potential impact on pack dimensions and the initial and ongoing flow-on cost implications.

[1] Refer to pages 7 and 10.

- The proposal that in the case of multi-ingredient products the 3 most abundant ingredients should be displayed on the front-of-pack would be nonsensical and potentially misleading.
- ASMI does not support the proposal that active ingredients be displayed on 3 non-opposing panels. Ingredient identification could be enhanced through alternative mechanisms.
- It seems likely that a standardised back-of-pack format for information ("Medicine Information Box") will facilitate consumer's ability to locate and identify the active ingredient and this should be taken into account when considering any changes to the front-of-pack.
- ASMI does not support the singling out of specific ingredients – instead a general QUM statement to address the issue of "doubling up" should be examined. The application of such a statement should be based on the risks associated with the product. ASMI acknowledges the risks associated with unintentional overdose, ASMI has concerns with the proposed warning statements for the front of pack in relation to paracetamol and ibuprofen. These are not the only risks with taking these products and in isolating one advisory statement on the front panel the consumer may miss other important information.

Notes on the Evidence Provided by the TGA

In support of the general statements about the risks to consumers from non-prescription medicines, the TGA has provided no evidence.

In support of the specific attention given to paracetamol and ibuprofen, the TGA has identified five references. ASMI's comments in relation these references are as follows:

Reference	Comments
Murnion (2010)	• This is a paper about the efficacy of combination analgesics (in particular the merits of combinations containing codeine). • The authors state that *"A significant proportion of cases of acute liver failure are from unintentional paracetamol overdose. Many of these patients have taken more than one paracetamol-containing preparation simultaneously".* • This one statement is a cross-reference to a 2005 US study. • There is no further examination of analgesic overdose or its causes in the paper. • The relevance of this paper to the risks associated with the labelling of non-prescription products in Australia is questionable.
Daly (2008)	• This paper describes the guidelines for the management of paracetamol poisoning. • The authors state that *"Paracetamol is involved in a large proportion of accidental paediatric exposures and deliberate self-poisoning cases, although subsequent hepatic failure and death are both uncommon outcomes".* • The paper includes no further examination of the causes of paracetamol poisoning (only focussing on the management of overdose). • The relevance of this paper to the risks associated with the labelling of non-prescription products in Australia is questionable.

Reference	Comments
Budnitz (2011)	• This paper summarises US Emergency Department visits for overdoses of paracetamol containing products. • The authors indicate that: *"Most emergency department visits for acetaminophen overdose were for self-directed violence (69.8%, 95% CI=66.4%, 73.2%)*". • The authors also state that: "*Therapeutic misadventures accounted for 16.7% (95% CI=14.0%, 19.5%) of visits and most involved overuse for medicinal effects (56.1%, 95% CI=50.6%, 61.6%) rather than use of multiple acetaminophen-containing products or dose confusion*." [emphasis added] • While the majority of visits relate to intentional overdose, in relation to therapeutic misadventure, the authors state that: "*To reduce the incidence of emergency department visits for therapeutic misadventures, interventions should target safe practices in the use of OTC medications by adolescents and young adults and safe use of acetaminophen-opioid combination products by older adults."* • The relevance of this paper to the risks associated with the labelling of non-prescription products in Australia (and the changes proposed by the TGA) is questionable.
Lavonas (2012)	• This paper examines the causal relationships between non-prescription analgesics and particular adverse effects (in an effort to determine which adverse effects can be attributed to which analgesics). • There is no examination of analgesic overdose or it causes. • The relevance of this paper to the risks associated with the labelling of non-prescription products in Australia is questionable.
King (2011)	• This paper presents the result of focus group testing in relation to active ingredient and dosing information on OTC labels of US paracetamol packs. • There is no examination of analgesic overdose or it causes. • Importantly the authors state that: "*Finally, this study describes only the development and not the testing of potential patient-centered icons and messages for acetaminophen."* • This paper is therefore of limited relevance to the risks associated with the labelling of non-prescription products in Australia.

ASMI further notes that previous reports (e.g. David Newgreen's 2003 analgesics review[2]) indicate that intentional overdosing with paracetamol reflects jurisdictional peculiarities. ASMI suggests that this is one area where it is not appropriate to automatically apply the data from one country to another. In the Introduction to the 2003 review, the author stated that:

[2] The Review of Non-prescription Analgesics - an update. Prepared for the Medicines Evaluation Committee by David B Newgreen. April 2003.

"the volume of recent literature on paracetamol is staggering, given the age of the drug. There are masses of data from all around the world about telephone calls to poisons information centres, presentations to hospitals, admissions, and on morbidity and mortality."

"What emerges is that it is not always appropriate to apply the legal requirements of one country to another. Even within one country, patterns of misuse may not be uniform."

Great care therefore needs to be exercised before implementing overseas measures. For example, the US controls on paracetamol are significantly different to the Australian controls (e.g. in the US, prescription paracetamol products are labelled as APAP, non-prescription paracetamol products are labelled as Acetaminophen, there is also no upper limit on non-prescription pack sizes).

Evidence from ASMI Members

ASMI members receive thousands of contacts from consumers every year through their customer information lines. Our members have reviewed their customer contact databases for issues with respect to non-prescription medicines labelling and there is no signal from the data showing that non-prescription medicines labelling poses a risk to consumers. Each member uses their own database so that collation of our member's data into an industry wide set has not been possible in the time allowed for this consultation.

ASMI members have extensive data showing that consumers buy non-prescription medicines by need state and then by brand. While active (and other) ingredient(s) feature in the decision making process, this is further down the hierarchy (along with price, product format, pack size, strength etc). Although there is some variation between product categories as to the rankings, the position of active ingredient is consistently below need state and brand (which consistently rank first and second). The data held by ASMI members is of a proprietary nature and so no further details as to the precise order of attributes can be provided here. Members may choose to provide this data (confidentially) in their own submissions.

Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	**Concerns**
1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name. 1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name. 1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name. 1.2.2 The font size of the active ingredient must be at least 100% of the font size of the medicine brand name on the main/front label.	<u>Clarifications required</u>: Based on the graphics in TGA's consultation paper it has been difficult to determine the exact detail of the proposal, we request clarification on: o The distinction between company name and brand name (i.e. are Swisse, Nature's Own or Cenovis the company or brand names?) with which prominence is proposed. This is confused by the TGA's examples of label graphics which allow different sizes for the company name, brand name and

Proposed Regulatory Change	Concerns
1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour. 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.	sub-brand. The prominence of active appears to be equivalent to the sub-brand. ○ While the text says the active ingredient must be immediately under the brand name, there is confusion what this means for the other requirements for presentation of active Ingredient and quantity or proportion as required in TGO 69. This is further confused by figures 2, 5, 8, 11, and 12 which all present this proposal differently. ○ What does this proposal mean for *Expression of quantity or proportion of active ingredient in medicines.* Is this proposal additional to the existing TGO requirement? Is the quantity and proportion of active also intended to be at equal prominence to the brand? Is the TGO requirement for expression of quantity or proportion of active moving into the Medicine Information Box? ○ TGO 69 currently requires minerals to be presented as elemental or compound quantity. ○ There will be issues with the length of names for herbal ingredients (e.g. length of the name itself, together with presentation as an extract/dry/fresh equivalent and the identification of the plant part). <u>Comments Generally</u>: • The stated intention of the proposals is to reduce the risk of accidental overdose. • Prescription and non-prescription issues need to be separated, as the active ingredient problem

Proposed Regulatory Change	Concerns
	from the evidence provided appears to relate only to prescription medicines. • All changes need to be based on risk. • The TGA has not demonstrated that equivalence in font size for active(s) and brand names is the only, or most effective, way to resolve this issue for non-prescription medicines. • Equal prominence of active ingredients with the brand name requires either a significant reduction in the brand size, reducing the consumer's ability to recognise the brand, OR a significant increase in pack size to maintain the brand visibility. • As discussed above, non-prescription shoppers generally select by category/symptoms, then brand (not active). For self-selection, consumers need the link between active ingredients, dosage and usage. The promotion of the size of the active ingredient over the statement of purpose of the product presumes the consumer's knowledge and understanding of pharmacology. • We note the impact on brand size will also have an impact on Signal Heading. • Equal prominence of active ingredients and brand name is more likely to create consumer confusion by increasing clutter and reducing legibility of label. The size of active is disproportionate and overwhelms the other information the consumer needs in order to make appropriate self-selection decisions. For Legibility – bigger does not necessarily equate to easier to read. • There is already limited free space on packs to facilitate navigation and this proposal will limit space even further. • Other ingredients are of relevance in the

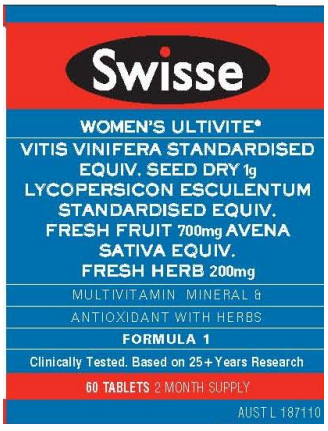
Proposed Regulatory Change	Concerns
	purchase/use decisions, e.g. excipients. • Any increase in pack size to accommodate larger active prominence will have flow-on cost implications to the entire supply chain • This proposal also undervalues other important information/cues non-prescription medicine labels currently provide to the consumer in the form of graphics on the main label, e.g. the appearance and type of the dose form (including which is the day tablet and which the night) and the inclusion and appearance of the type of measuring device. • As with all corporate logos and designs, label designs also have rules. Global branding designs will not be formulated to accommodate Australian labelling requirements. The designs can also provide the basis for pictorial communication to the consumer e.g. a Day and Night product. <u>Complementary medicines:</u> • These products are regulated as dietary supplements overseas, not therapeutics. This limits the relevance of overseas data and raises the possibility that the proposed changes will have an impact on competition. <u>Low risk topical OTC products</u> (e.g. sunscreens and toothpastes) • The stated intent is to reduce the risk of accidental overdose. No such risk exists with these products. • These products are not associated with systemic

Proposed Regulatory Change	Concerns
	absorption. • These products pose a limited safety risk (excluding hypersensitivity). • The prominence of the SPF for sunscreens will be overwhelmed by prominence of active. • Sunscreen active ingredient names are long and could potentially scare consumers into not purchasing/using a sunscreen (this could have a negative public health outcome). • These products are regulated as cosmetics overseas. This limits the relevance of overseas data and raises the possibility that the proposed changes will have an impact on competition.

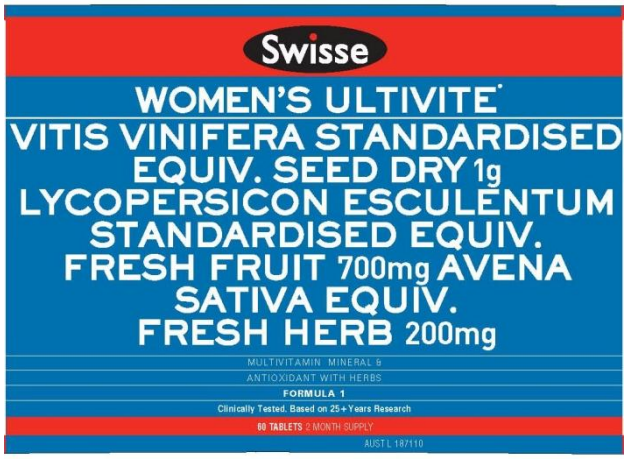
EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW

Graphic 1 Clarification of Company Name and Brand Name and impact of herbal names

Main Panel of Current Label



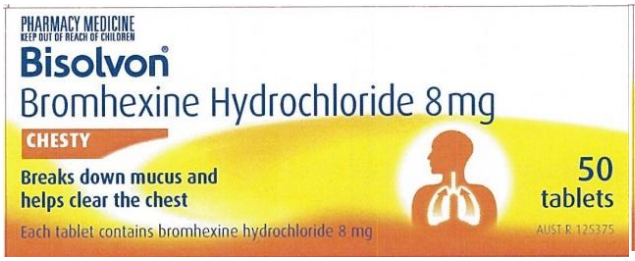
Prominence of Actives 100% of Product Name



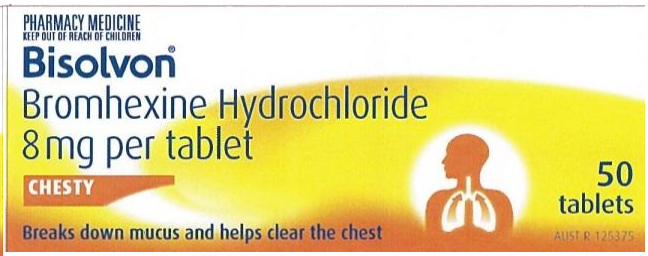
Prominence of Actives 100% of Product Name

Figure 2 Clarification *Expression of quantity or proportion of active ingredient in medicines* –Tablets

Current TGO 69 requirements
for Expression of Actives



Prominence of actives with existing expression of proportion of actives as currently required



Prominence of actives with expression of proportion all at 100% of brand name

Graphic 3 Impact of Proposal 1.1 and 1.2 on Brand visibility – Listed Complementary Medicine

Graphic 4 Impact of Proposal 1.1 and 1.2 on Brand visibility – OTC Registered

Graphic 5 Impact of Proposal 1.1 and 1.2 on Brand visibility – OTC Registered

Graphic 6 Impact of Proposal 1.1 and 1.2 on Brand visibility – OTC Registered

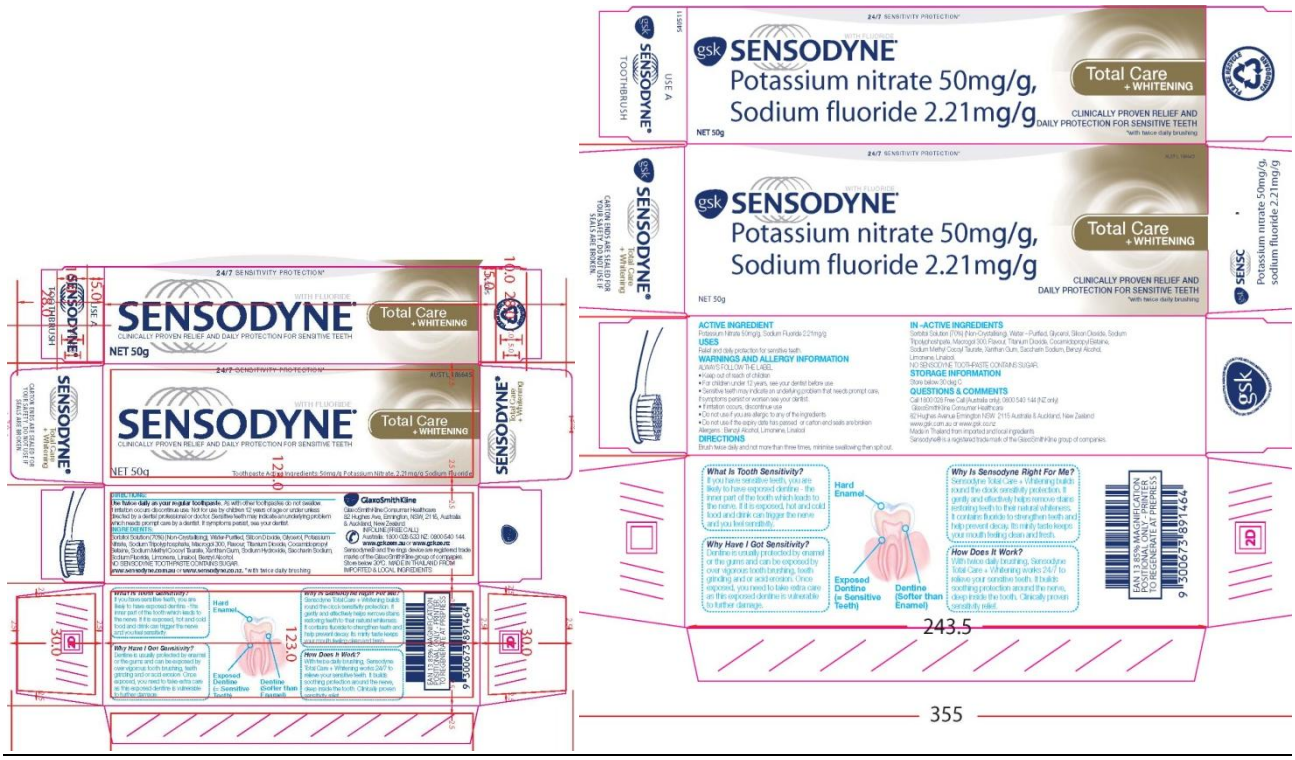
Graphic 7 Impact of Proposal 1.1 and 1.2 on pack size to maintain brand visibility

Impact of implied requirement in figure 2 for inclusion of Company name.

Graphic 8 Impact of Proposal 1.1 and 1.2 on other important cues – Listed Complementary

Graphic 9 Impact of Proposal 1.1 and 1.2 on Low Risk Medicines – Sunscreens

Graphic 10 Impact of Proposal 1.1 and 1.2 on Low Risk Medicines – Toothpastes



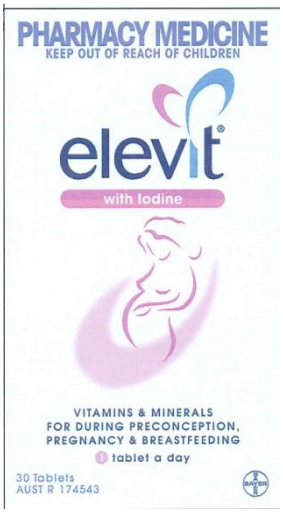
Proposed Regulatory Change	**Concerns**

1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names, together with the quantities of every active ingredient, are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)	• It is unclear from the proposed change how many of the most abundant ingredients are to be included. ASMI has assumed that the intention is to include the three most abundant active ingredients.
	• It is unclear how this proposal fits with proposal 1.5.
	• The TGA has not provided evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.
	• For multi-ingredient products, just having 3 ingredients on the front panel is nonsensical, misleading and will confuse consumers about the contents and intended use of the product.
	  ○ It also implies that the highest quantity ingredients are more important or more potent in the formulation.
	  ○ It may mislead consumers into ignoring the hypersensitivity issues of other ingredients (e.g. topical products).
	  ○ It may lead consumers to overlook products which are intended for the purpose they require. (e.g. in the Elevit pregnancy supplement, folate would not be listed on the front panel, and the 3 most abundant actives are calcium, magnesium and phosphorus).

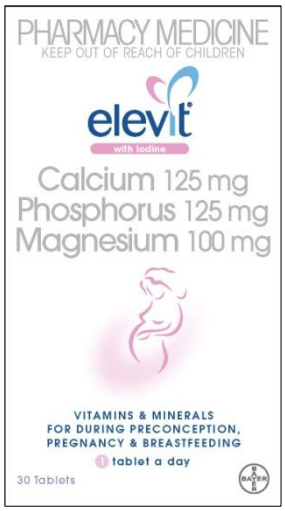
EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW

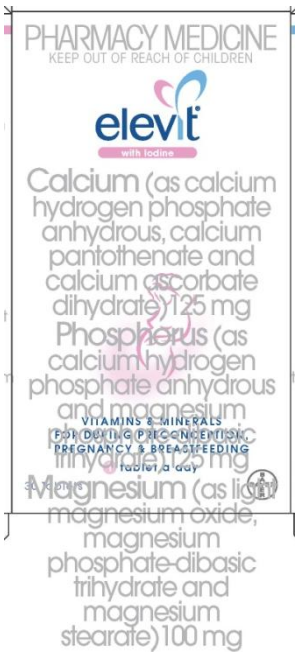
Graphic 11 Impact of proposal 1.3, & Clarification Expression of quantity of active ingredient–Trace Elements

Current Carton Main Panel



Proposal 1.3 Carton Main Panel





Issues with TGO 69 Requirements for expression of Trace Elements

Proposed Regulatory Change	**Concerns**
1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2mm in height on the main/front panel.	• ASMI is pleased that the TGA has taken some steps to accommodate the complexities associated with Day and Night preparations. • The concerns expressed above apply here.

EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED ON THE FOLLOWING PAGES

Graphic 12 Impact of proposal 1.4 & 1.5, Global Design Impact & loss of graphics cues

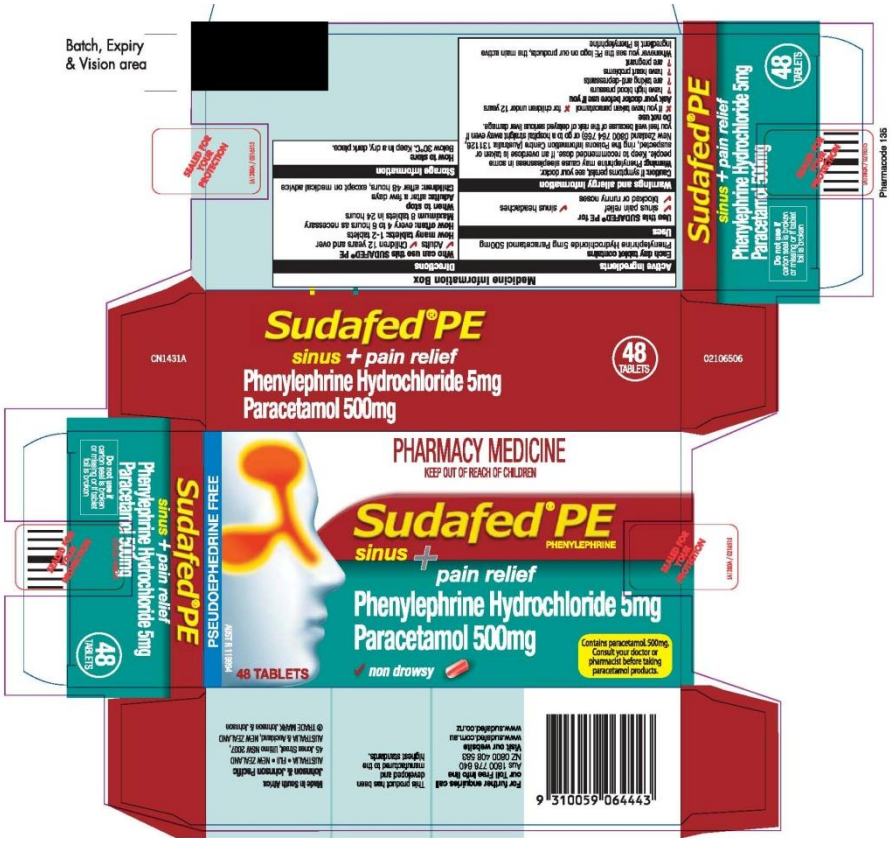
Current Label Artwork

Impact of Proposals 1.4 & 1.5

Proposed Regulatory Change	**Concerns**
1.5 The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.	• The TGA has not justified the need for this proposal on non-prescription medicines. • This requirement appears to be an attempt to address issues with the prescribing and dispensing of prescription medicines. • This is applying a pharmacist's storage and dispensing issue to non-prescription medicines. • It is difficult to understand how it assists the consumer in self-selecting medicines. Non prescription medicines will be displayed in a category on shelves and will be selected by brand. • Taken together, the proposals in the Consultation paper will require non-prescription medicines in cartons, to declare the active ingredients on the front, the back, and two other non-opposing faces. Repeating all this information on four of the six carton faces is unnecessary and wastes the limited space available.

EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED ON THE FOLLOWING PAGE

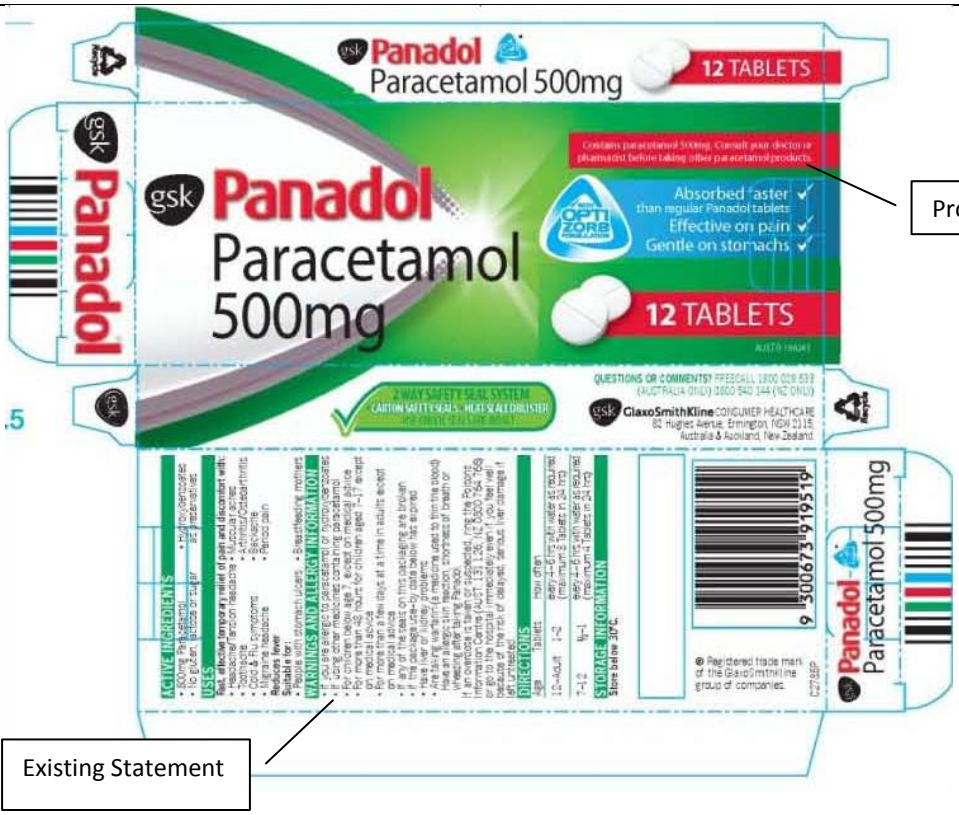
Graphic 13 Impact of proposal 1.5



Proposed Regulatory Change	**Concerns**
1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging: "Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."	• The Consultation paper presents this advisory statement as a new requirement for paracetamol in Australia. Words to this effect have in fact been on the back of pack since 2004. The paper presents the Australian labelling to be out of step with the rest of the world. • It is unclear why the TGA is proposing that this advisory statement for paracetamol is to be duplicated on the front label. • The TGA has provided evidence of similar statements from overseas. But have not provided any assessment of their success. • In the Consultation paper it is unclear whether the overseas requirements relate to duplicate warnings or whether the warnings are required on front of pack. It is ASMI's understanding that the UK and the US require a warning similar to the current Australian statement and that neither the UK nor the US require this warning on the front of pack (as is implied in the Consultation paper). • A warning against concomitant use of other paracetamol products is already required on packs in Australia. • These are not the only risks with taking these products, and there is concern that by isolating these statements to front of pack, the consumer may miss the other important information (or assume that this is the only important information). • Isolating this warning on front of pack is inconsistent with the grouping of information evident in the Medicine

Proposed Regulatory Change	Concerns
	Information Box proposal.
1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging: "Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."	• The Consultation paper presents this advisory statement as a new requirement for ibuprofen in Australia. Words to this effect have in fact been on the back of pack since 2005. The paper presents the Australian labelling to be out of step with the rest of the world. • It is unclear why the TGA is proposing that warning statements for ibuprofen are to be duplicated on the front label. • The TGA has provided no evidence of similar statements from overseas. • A warning against concomitant use of other ibuprofen or other non steroidal anti-inflammatory products is already required on packs in Australia. • These are not the only risks with taking these products, and there is concern that by isolating these statements to front of pack, the consumer may miss the other important information (or assume that this is the only important information). • Isolating this warning on front of pack is inconsistent with the grouping of information evident in the Medicine Information Box proposal. • The TGA has provided limited evidence of concerns surrounding paracetamol, but have provided no evidence in relation to any other active. It is unclear why ibuprofen has been included in this requirement.

EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW



Graphic 14 Impact of proposal 1.6

Existing Statement

Proposal 1.7

Graphic 15 Impact of proposal 1.7

Importantly all the previous graphics reveal the profound impact that the proposed changes will have on brand recognition, pack clutter and pack size for non-prescription products.

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals

- For non-prescription medicines, due prominence of ingredient names can be achieved in other ways (Use of colour, graphics, consistent positioning and different font types and sizes) and should be investigated. ASMI's alternate proposal is:
    - A standard band in a contrasting colour at the bottom of the front panel of the label for inclusion of the actives to facilitate recognition through consistent placement and presentation.
    - The size of the font of the actives could be achieved using a "scaling approach" (e.g. similar to the approach taken for signal headings) and making these proportional to available label space (height/area) to make this practicable in the case of smaller packs.
- This proposal accommodates Day and Night products, but may require an option for a minimum font height.
- For multi-ingredient products we suggest the standard band at the bottom of the Front panel instead provide a 'referral' statement, e.g. "See side (or rear) of pack for the active ingredients (Medicine Information Box)".
- It seems likely that a standardised back-of-pack format for information ("Medicine Information Box") will facilitate consumer's ability to locate and identify the active ingredient and this should be taken into account when considering any changes to the front-of-pack.
- Sunscreens and toothpastes are arguably at the lowest end of the risk continuum and ASMI is not aware of any risks in relation to this category of products. We propose maintaining the current TGO 69 requirements in relation to low risk products.
- For small containers a minimum font height should be considered appropriate.
- A standardised statement in relation to the risks associated with taking more than one medicine containing the same ingredient. The application of such a statement should be based on the risks associated with the product.
- Non-regulatory approaches to mitigate risks must also be considered. Consumer education is a critical element in enhancing QUM. This would be consistent with Recommendation 14 in the ACSQH Report: "*Educate consumers on medicines names and label content and where to locate further information*"[3].

Caveats

The figures in the Consultation paper are flawed and have hampered the consultation process (for a full discussion see Appendices 1 and 2). Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

[3] Refer to page 7 of the ACSQHC report provided at Appendix 4

Look-alike and sound-alike medicine brand names and look-alike packaging and branding

Stated Objective(s)

The consultation paper states that the objective of the Review is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

- Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicines branding (also called brand extension, umbrella branding or trade name extension);
- Medicine names that look-alike and sound-alike (LASA) that can lead to use of the incorrect medicine
- Medicine containers and packaging that looks like that of another medicine.

Stated alternatively:

- To reduce the risk of accidental overdose that could result from consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines

Consumer risk(s) identified in the consultation paper

The Consultation paper indicates that: "*Key risks to consumers from LASA brand names result when they are accidentally given the wrong medicine by a pharmacist or health care professional or they select the wrong medicine themselves due to the similarity of the name or packaging of a medicine.*"

The Consultation paper also states that: "*there is also a risk of overdose if the consumer takes a product containing the same active ingredient but is marketed under a different name."*

Summary of ASMI Position

- While ASMI fully endorses the objective of avoiding possible harm which may result from confusing different medicines, we do not support the blanket and simplistic approach to both prescription and non-prescription medicines advocated in the consultation paper.
- Distinction should be drawn between proposals in relation to prescription and non-prescription medicines. The paper confusingly amalgamates four interrelated issues into a single topic applicable to both prescription and non-prescription products. The four issues (look-alike sound-alike products; different strengths within a prescription medicine brand; umbrella branding; indication specific branding) all apply differently to prescription and non-prescription medicines.
- This is a complex and multi-faceted area for non-prescription medicines in particular. Branding and brand recognition through brand extension ("umbrella branding") are key issues for non-prescription medicines, both from an industry viability perspective but equally importantly from

the consumer self-selection perspective. The costs associated with establishing a novel non-prescription medicine brand (as well as developing consumer awareness and trust) are considerable. These costs will be a key determinant in the decision to launch a new product. Inappropriate restrictions on umbrella branding will have a detrimental impact on access to new products.

- Consistent with a risk-based approach, proposals should be reflective of the risks posed by the different categories of products. For example, the potential risks associated with ingesting a medicine are different from those associated with topical application of a product.
- ASMI remains available to work with the TGA to develop appropriate guidelines and protocols to assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.

Notes on the Evidence Provided by the TGA

In support of the general statements about the risks to consumers of the look-alike and sound-alike names, packaging and branding of non-prescription medicines, the TGA has provided no evidence.

In support of this entire section of the consultation paper, the TGA has identified a single reference. ASMI's comments in relation this reference is as follows:

Reference	Comments
Australian Council for Safety and Quality in Health Care (2002) Second national report on patient safety. Improving medicine safety.	• This report focuses almost entirely on incidents that relate to prescribing, dispensing and administration by healthcare professionals. • The strategies identified as having been shown to reduce medication incidents deal with systems and processes to be employed in hospitals, surgeries and pharmacies. • The examples given of look-alike and sound-alike issues are of prescription products. • An example is given (page 37) of the potential confusion between "Panadol" and "Herron" paracetamol products. However, this example is presented in the context of a pharmacist dispensing a generic medicine and at this point the authors state: "While this has the potential to lead to adverse drug events that result in patient harm, no data are available on the extent to which this occurs." • This paper is therefore of limited relevance to the risks associated with the labelling of non-prescription products in Australia.

Evidence from ASMI Members

ASMI members receive thousands of contacts from consumers every year through their customer information lines. Our members have reviewed their customer contact databases for issues with respect to non-prescription medicines labelling and there is no signal from the data showing that non-prescription medicines labelling poses a risk to consumers. Each member uses their own database so that collation of

our member's data into an industry wide set has not been possible in the time allowed for this consultation.

ASMI members have extensive data showing that consumers buy non-prescription medicines by need state and then by brand. While active (and other) ingredient(s) feature in the decision making process, this is further down the hierarchy (along with price, product format, pack size, strength etc). Although there is some variation between product categories as to the rankings, the position of active ingredient is consistently below need state and brand (which consistently rank first and second). The data held by ASMI members is of a proprietary nature and so no further details as to the precise order of attributes can be provided here. Members may choose to provide this data (confidentially) in their own submissions.

Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	**Concerns**
3.1 Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names. 3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements. 3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine. A well known combination product that contains paracetamol under a particular umbrella brand name would not be able to use this same umbrella brand name for another combination product that	**<u>Look-alike and sound-alike medicine names</u>** **<u>Look-alike medicine packaging</u>** • The stated intention of the proposals is to reduce the risk of consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines. • Evidence provided on LASA in the consultation document relates to prescription medicines only. • Prescription and non-prescription issues need to be separated, as this issue appears to relate only to prescription medicines. • All changes need to be based on risk. • The proposed changes are applied arbitrarily. • Proposal 3.1 arbitrarily assumes that all products carry the potential for confusion based on look-alike sound-alike (LASA) issues. • The proposed changes ignore the higher risks (and different safety profiles) of prescription medicines in comparison to non-prescription medicines by failing to recognise that: o Dispensing errors relate to prescription medicines

Proposed Regulatory Change	Concerns
also contains ibuprofen.	○ Consumers can be confused between the branded and generic prescription medicines - this is also a prominence of active issue ○ Non-prescription medicines have detailed information on the labelling (prescription medicines do not). ○ Prescription medicines do not include information about the product purpose on their labels. ○ Non-prescription medicines are placed in therapeutic categories in pharmacies and grocery, e.g. Zyrtec and Zantac would be stored separately. ○ Non-prescription products with similar sounding active ingredients, e.g. loratadine and loperamide would be stored with other allergy and anti-diarrhoeal products respectively. There would be minimal risk of confusion. ○ As discussed above, consumers buy their non-prescription medicines by brand and indication, not according to active ingredients. ○ Pharmacists select and dispense prescription medicines, whereas the consumer often self-selects non-prescription medicines. ○ With Pharmacist-Only medicines, the pharmacist provides the product either based on specific request from the consumer or on recommendation for symptoms. • Requiring a specific brand name or brand colours and design for Australia will have Trademark implications for global brands. An Australian specific name or design will have ongoing cost implications arising from the unique printing requirements.

Proposed Regulatory Change	Concerns
	• Non-prescription medicines use brand names, designs and colours and other cues to differentiate from other products. • Non-prescription medicine branding has not only the investment in the design but also the investment in establishing consumer brand recognition developed over years. Proposal 3.3 to retrospectively apply LASA principles at any change to labelling of an existing product is an unfair approach and disregards the sponsor's investment in the brand, regardless of the length of time a product has been available and its safety record. This could penalise a product that was available prior to other products with a similar name or pack colouring. Consumers are very sensitive to changes in branding. Significant changes to brand design and pack colours makes the consumer doubt whether they have the same product. • Proposal 3.3 if applied across all medicines would unfairly impact non-prescription medicines with prior approval changes to label being a more frequent event than for prescription medicines. • The proposed changes will impact directly on the Brand names and design features used on labelling. The trademark implications of the proposed changes will need to be thoroughly examined. This is a complex legal area. The Consultation paper ignores the protections currently afforded to both manufacturers and consumers by the registration and maintenance of trademarks. The Consultation paper also ignores the impact that retrospective changes to brands, colours and designs will have on existing trademarks. • If a blanket approach is to be applied o The proposed method to electronically screen brand names is based on US software. Evidence is required; firstly

Proposed Regulatory Change	Concerns
	that the software works in the US and, secondly, that the software will work for Australian names and pronunciations. ○ Any brand recognition software should also be accessible to industry for planning purposes. ○ Clear and objective guidelines for LASA should be developed in association with industry and other relevant stakeholders. ○ LASA should not be applied retrospectively. • LASA issues extend beyond medicines to cosmetics, devices and foods.
3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.	**<u>Look-alike medicine branding, also known as brand extension or trade name extension</u>** **<u>[AUST R/AUST L]</u>** • This requirement is arbitrary and makes no more sense that applying a similar restriction based on scheduling (i.e. preventing S2 and unscheduled products having the same name). The TGA has not provided any rationale for this requirement. • Some complementary brands already have products that range across the AUST R and AUST L classifications based on scheduling or indication (e.g. Centrum). There is no evidence that this practice causes harm. • Some other non-complementary brands have products that range across the AUST R and AUST L classifications based on indication or active ingredient (e.g. Dencorub, Neutrogena, and Blistex). There is no evidence that this practice causes harm. Neutrogena is about skin care. The Brand spans AUST R, AUST L and cosmetic products. Further to this, if a brand was already associated with listed lip care products, there

Proposed Regulatory Change	Concerns
	ought to be no reason to prevent that brand from also including a registered cold sore cream. • Another example is MOOV head lice range, which includes products classified as cosmetic (defence spray), AUST L (helps detect head lice and remove eggs), AUST R (kills lice and eggs) and a device (treatment by suffocation). All these products are for head lice but have different claims. This helps consumers identify, within a brand range, what treatment options are available for each stage of infestation. There is no evidence that this practice causes harm. • Clarification is required as to whether export only products (which are AUST L) are included in this proposal (i.e. will sponsors require different names for the export only and the domestic products). • Clarification is required as to whether kits that include AUST R products will be impacted by being listed under the same brand name.
3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom. For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity. 3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met: a. The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and b. The safety profile, efficacy and dosage regimen are similar.	**Look-alike medicine branding, also known as brand extension or trade name extension** **[Different actives and indications]** • It is unclear as to what is meant by 'brand name'. Does this include the corporate name (e.g. Chemists Own, Terry White Chemists, Herron, and Swisse)? Does it include different formats of the same products (e.g. slow-release)? The TGA should clarify this. • Sunscreens and toothpastes have multiple actives, often more than 3, and the need to change the brand name for each variation is not justified from a safety perspective. These products are at the therapeutic/cosmetic interface and they would be at a commercial disadvantage, due to fragmentation of the sunscreen market and difficulty achieving listing

Proposed Regulatory Change	Concerns
Examples of the application of the above requirements include: A brand name that has historically been strongly associated with a particular anti-histamine would not be permitted to be used for a new product with a different type of active ingredient, such as a corticosteroid or a different anti-histamine.	in major stores. This proposal could therefore restrict competition. • No evidence is provided in the Consultation paper to demonstrate consumer confusion. • Umbrella branding issues are very situational and depend on the category, brand, packaging, graphic area/space and brand history (heritage). • Blanket restrictions such as this are likely to stifle innovation. • Non-prescription products include different cues to help consumers differentiate between products: o packaging and labelling ▪ brand, sub-brand and indication, including strengths of active ingredients, e.g. hydrocortisone 0.5% and 1.0%, and directions for use ▪ structural, such as size, orientation, shape ▪ differentiation in graphics, colour, font, flags, etc o form and dose differentiation ▪ colour of dose ▪ embossing/printing on dose ▪ shape ▪ coating • Any decision making process needs to be objective, not subjective and based on published guidelines. • The resulting proliferation of brand names will be associated with increased costs to register and maintain brands (in terms of the trademarks themselves and the development of

Proposed Regulatory Change	Concerns
	brand awareness). On this point the cost of innovation equals the cost of new product development plus the cost of new (and additional) brand development. • Testing of labels with consumers is expensive, any such requirements should be risk based. • As discussed above, non-prescription shoppers generally select by category/symptoms, then brand (not active). • Most complementary medicines are effectively umbrella branded (e.g. Swisse, Blackmores, Cenovis, and Nature's Own). Consumers shop by brand and indication, rather than ingredient. Even if they are looking for a specific ingredient (e.g. calcium, folic acid, vitamin D) consumers seek out brands they know. • Complementary medicines are recognised as having low risk. RASML requires label warning statements where necessary. The proposal for a standardised format on the back label will help ensure that these are seen by consumers
	<u>Look-alike medicine branding, also known as brand extension or trade name extension</u> **[Indication specific branding]** • The stated intention of this proposal is to reduce the risk of accidental overdose. • All changes need to be based on risk. • Whether or not there is a risk of accidental overdose, there are good examples of when indication-specific branding is useful and helps the consumer identify the appropriate product. • If the purpose of the product speaks to the consumer's need (e.g. miconazole 2% for tinea, jock itch and thrush) then sub-branding by indication is justified as men do not want to use a female hygiene product or a tinea product for jock itch. These are

Proposed Regulatory Change	Concerns
	embarrassing conditions and consumers would often prefer to be able to find a suitable product quickly and without a fuss. This branding approach allows products with similar indications to be grouped together in the retail environment. • The TGA has not made clear what 'specific characteristics' might mean (in proposal 3.5) in relation to making a product more suitable for a particular symptom. Does this mean: o A faster acting formulation or salt o Extended release formulation o Products for different population age groups, e.g. children's medicines o Flavour variations within a range o Dose formats, e.g. tablets, capsules, liquids, effervescent dose forms, patches, gums, etc o Different packaging delivery system, e.g. nasal drops vs. nasal spray; liquid preps with a spoon vs. syringe dosing device • It appears that one of the inevitable consequences of these requirements will be that sponsors have to declare all the indications on the label. For complementary medicines in particular this will be confusing for consumers. For example a fish oil product may be indicated for a range of conditions (sometimes with different doses) and it would be confusing to have to list all indications and doses on the one label. Similar issues would arise with many other supplements.
Importantly, blanket prohibitions are not appropriate here. What are needed are guidelines and protocols which assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.	

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- Consistent with a risk-based approach a distinction should be drawn between the different non-prescription medicines categories. We do not support a blanket approach to be applied to all non-prescription medicines.
- Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- As the risks are different for the different medicines categories, the requirements should also be different.
- Non-regulatory approaches to mitigate risks must also be considered (e.g. consumer education).
- The TGA should separate out the prescription and non-prescription issues.
- Given the complexity of these issues (and in view of the above) ASMI feels strongly that this area requires more in depth exploration and consultation with all stakeholders to generate confidence that reforms will achieve the stated objectives and not result in unintended consequences.
- The TGA in collaboration with consumers, industry and other stakeholders should pursue the development of guidelines for LASA and brand extensions ("umbrella branding"). Clear guidelines and protocols would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.
- The following items could be addressed in the guidelines:
    - The role of prefixes and suffixes
    - The use of sub-branding
    - The use of colours and graphics and different fonts
    - The use of icons
    - The relevance of different dosage formats
    - Flagging actives, indications in a standard format
    - The prominence of the active ingredient
    - The standardised Medicine Information Box
    - A flow chart as to when umbrella branding issues apply and are relevant
    - A Labelling Code of Practice
    - Agreed protocols for testing labels with consumers,
- The TGA should consider the merits of making these guidelines as accessible as possible.
- Additionally, ASMI believes that evidence-based and objective decision-making would be greatly enhanced by the development of a broadly acceptable label testing methodology. The aim of such a methodology would be to generate tests results that would provide confidence that any risks in relation to product identification and other issues impacting on safe use have been effectively addressed.

- Testing protocols could address the following:
  - when testing is required (i.e. should not be required for all non-prescription products)
  - any category specific requirements
  - sample sizes
  - pass/fail criteria
  - benchmarking
  - comprehension testing
  - product selection and product use (at the point of sale, in the home)
- ASMI proposes that the TGA commissions a paper on international best practices for label comprehension testing.
- The TGA should consider the impact of a standardised back-of-pack on the consumer's ability to locate and identify the active ingredient and factor this into any proposals affecting front-of-pack.
- The TGA should consider a standardised statement in relation to the risks associated with taking more than one medicine containing the same ingredient. The application of such a statement should be based on the risks associated with the product.
- The TGA should consider exempting non-prescription medicines from the LASA requirements as the risk has only been demonstrated for prescription products.
- The TGA should consider exempting sunscreens and toothpastes from any umbrella branding requirements.
- All changes should acknowledge the fact that non-prescription packs are already differentiated with colour, graphics, font type and size to help consumers find brands. This, in part, relates to trademark issues but there are more differentiating features on non-prescription packs than on prescription packs due to the nature of the information that needs to be conveyed to the consumer.
- The TGA should consider exempting existing brands from having to change the colour of their packaging.
- The TGA should work with industry and relevant stakeholders in the development and introduction of any brand recognition software. Any developed brand recognition software should also be accessible to industry for planning purposes
- The TGA should only apply revised requirements to new medicines, not retrospectively.
- The TGA should consider the merits of testing methodologies used in other comparable jurisdictions.
- The TGA should consider indication-based umbrella branding for combination products in some categories, taking into account brand history (e.g. cough/cold, sunscreens).

Caveats

As mentioned earlier (see Appendices 1 and 2), this section of the Consultation paper co-mingles prescription and non-prescription requirements, issues and proposals. Furthermore the related figures are flawed and have hampered the consultation process. It has therefore been difficult to clearly identify the scope of the Consultation paper. Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

Standardised information format: the Medicine Information Box

Stated Objective(s)

The consultation paper states that the objective of the Review is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

- There is a lack of standardised format for information included on medicines labels and packaging
- Information about the active ingredient(s) contained in the medicine is not always easy to find;
- Inconsistent placement of information such as dosage and usage instructions, precautions (including potential allergens) and storage instructions increases the risk that a medicine may be taken or stored inappropriately.
- Consistent formatting and presentation of information will assist consumers to identify and interpret the information they need.

Consumer risk(s) identified in the consultation paper

The consultation paper indicates that: "*Inconsistent placement of information such as dosage and usage instructions, precautions (including potential allergens) and storage instructions increases the risk that a medicine may be taken or stored inappropriately*."

Summary of ASMI Position

- ASMI agrees that a standardised back-of-pack has some merit, however the details need to be properly developed. Some flexibility needs to be incorporated and the designs must be based on the outcomes of consumer testing.

Notes on the Evidence Provided by the TGA

In support of this entire section of the consultation paper, the TGA has identified a single reference. ASMI's comments in relation this reference is as follows:

Reference	Comments
Shrank (2007)	• This paper is a review of studies into the content and format of prescription labels. • The relevance of this paper to the risks associated with the labelling of OTC products in Australia (and the changes proposed by the TGA) is questionable. • The authors summarised their findings as follows: "We performed a systematic review of the published literature to evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. The evidence suggests that patients request information about a

Reference	Comments
	medication's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. There was little evidence to link label design or contents to measurable health outcomes, adherence, or safety."[emphasis added]

Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	Concerns
4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are: • Active ingredient, including the amount in each dosage unit • Uses (indications) • Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor or pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.) • Directions/Dosage instructions • Storage information. 4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm. 4.3 The Medicine Information Box must have a white background with black text. Headings must be highlighted or bolded so they are sufficiently emphasised. 4.4 Where there is insufficient room on a single face of a package, the box may be split over more than one face. However, the overall format of the information is to remain the same. In these instances a pack insert may also be included containing the Medicine Information Box as a continuous table.	• The TGA acknowledges that the proposed change is based on the US FDA requirements, however, no evidence has been provided as to the success of the US model. • Many Australian non-prescription labels have been developed as a result of consumer testing. Such testing provides evidence that the labels perform well from a consumer usability perspective. • The TGA does not appear to have drawn upon the work already done in relation to Australian labels. • While a standardised back-of-pack may appear acceptable in principle there are many issues with the details. • Many products already need to include a lot of information on their label. This proposal adds the requirement to include the active ingredient again, as well as 2mm height for each heading and a title of 'Medicine Information Box'. This is particularly relevant for bottle labels. • The proposed format will result in the wrapping of warning statements, rather than one warning per line which will reduce legibility.

Proposed Regulatory Change	**Concerns**
4.5 Information about the presence in the medicine of an allergen listed in Schedule 1 of TGO 69, which may be amended, must be included under the heading Warnings and Allergy Information. 4.6 For products containing more than 3 active ingredients, or products in small containers, there may be insufficient space on the medicine container or primary packaging for a complete Medicine Information Box. In these cases a complete Medicine Information Box should be included as a pack insert. The minimum information to be included on the label will include information under the following headings: • Directions • Warnings and Allergy Information. Where space restrictions do not allow for the required information to be provided in the Medicine Information Box, an alternative arrangement or formatting of information should be provided to the TGA for assessment and approval, together with a justification for non-standardised presentation. This may include breaking the information over more than one panel, or reduction in font size.	• All language used should be consumer friendly. • The title 'Medicine Information Box' is too restrictive for complementary products and AUST L topical products such as sunscreens and toothpastes, which are regulated as dietary supplements and cosmetics respectively in overseas jurisdictions. • The need to give the information on the rear panel the title 'Medicine Information Box' or any other title is questioned. Current packaging has the medicine information on the rear panel, and consumers already know where to look for it. If a title is determined as necessary it should be 'Consumer Information'. The term 'Box' should be omitted as it may be broken over two panels. • A standardised back-of-pack, as proposed, may have an impact on exports of Australian labelled product. If a single pack for multiple markets cannot be developed then certain products may no longer be commercially viable (noting that a single pack may not be possible for a number of reasons such as the use of the term "medicine" in relation to an unregulated product in the receiving market or because it is not possible to fit all the requirements of both markets on the one label). • The proposal is not practical for small containers. It is unclear whether the proposal applies to small containers or whether there will be exemptions for these. <u>Mandatory Headings</u> • A risk based flexible approach may be necessary as some of the headings may not be appropriate for all product categories. • ***Active Ingredient*** **mandatory heading:** it may be

Proposed Regulatory Change	Concerns
	preferable to group the active and required inactive ingredients (as per TGO 69, First Schedule) together under a more consumer focussed heading, e.g. 'Each [dosage unit] contains' or 'This product contains' (for topicals). Inclusion of these statements together will ensure that the consumer easily finds any ingredient information, especially when they need to take care and avoid an ingredient due to a sensitivity, allergy or intolerance. • ***Uses*** **mandatory heading:** ASMI agrees the indications are a primary piece of information for the consumer in self selecting the product and should be located at the beginning of the information panel. • ***Warnings and allergy information*** **mandatory heading:** • Testing of labels to achieve consumer-focused labelling found that terminology such as 'Do not use' and 'Before you use' are better understood and not as alarming to consumers. These headings allow for grouping of statements as dot points directly beneath them, and reduce label clutter. We question the use of the term 'Warnings'. We also question the grouping of the Advisory Statements with the Statements required by the First Schedule of TGO 69 and the use of the term 'Allergy' in the heading. Many of the statements required by the First Schedule of TGO 69 deal with specific ingredient intolerances, rather than allergic reactions. This heading

Proposed Regulatory Change	Concerns
	of *Warnings and allergy information* may cause a misunderstanding or even overlooking of ingredient information provided – We suggest the First Schedule Statements would be better located with the Active ingredient. Refer comments above in Active ingredient mandatory heading. • ***Directions*** **mandatory heading:** We need to maintain flexibility in the way this information is presented to accommodate requirements of different dose forms, e.g. tabulation of age/weight dosing. • ***Storage*** **mandatory heading:** This is an unnecessary heading for currently required information. It is also noted that the Figures in the paper imply: o additional CMI-type storage statements to the label. e.g. 'Protect from moisture' and 'Protect from light and moisture'. TGO 69 specifies permitted storage statements. o the requirement for a description of the products which would seem to be inappropriate and outdated. Many products provide an accurate graphic depiction of the dosage form on the main panel so the consumer can accurately identify the product. This depiction is more useful to the consumer than a

Proposed Regulatory Change	Concerns
	description in words. • **Formatting of the Medicine Information Box:** Industry is not in favour of mandated black and white for the information panel. We understand that the FDA allows contrasting colours. While it is agreed black on white text is the preference for ease of reading, the highlighting of the headings should be allowed to be done in a contrasting Brand colour, e.g. the current Panadol pack. The use of colour and inclusion of the brand name adds to the distinctiveness of the pack, an ARGOM requirement. It will also help the consumer differentiate between products when comparing side-by-side. • It is important to understand that for scan-ability of barcode, the barcode needs to be at 100% magnification and cannot be truncated (cut down in height). The barcode therefore cannot always be placed on side panels of cartons. The size of the barcode is not negotiable and on small packages like tablet cartons this can take up a large area of the panel. Barcodes must be produced to the GS1 standard and the label requires a GS1 Certificate to be presented as proof of scan-ability for ranging a product with some retailers. <u>Insufficient room on a single face</u> • We welcome the opportunity to split the medicine information over more than one panel. • We note that the sponsor may include a pack insert with the information in a continuous table if they wish. However, we would be concerned if

Proposed Regulatory Change	Concerns
	this was mandated in a TGO or by an evaluator. • The requirement to include a pack insert adds additional cost to the product and needs to be justified. Additionally, where a pack insert already exists, it may include information not required at the point of purchase or it may be the Consumer Medicine Information (CMI) leaflet. In either of these instances, the additional inclusion of Medicine Information Box formatted information would be extremely confusing. • In response to Proposal 4.5 Refer ASMI comment for 'Warning and allergy information' mandatory heading. We would appreciate clarification of what is meant by 'which may be amended' in reference to the First Schedule of TGO 69. To include this under the proposed regulatory changes with no detail is inappropriate and makes it difficult to comment. <u>For Medicines containing more than 3 actives or in small product containers.</u> • While pleased that TGA has identified that there may be an issue for products with more than 3 ingredients or more for small containers, it will be a challenge for complementary medicines, in particular, to list all the ingredients or herbal equivalents on the label, as well as other mandatory information. • Often these products are in labelled bottles, not cartons. To require a pack insert will necessitate additional packaging, which will increase the cost of the product for consumers, and increase the environmental footprint.

Proposed Regulatory Change	Concerns
	• The need to justify a change in formatting such as breaking the information over more than one panel appears to contradict with the information presented above in proposed regulatory change 4.4, which advises that information can be located elsewhere on the pack. This requires clarification.

EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW

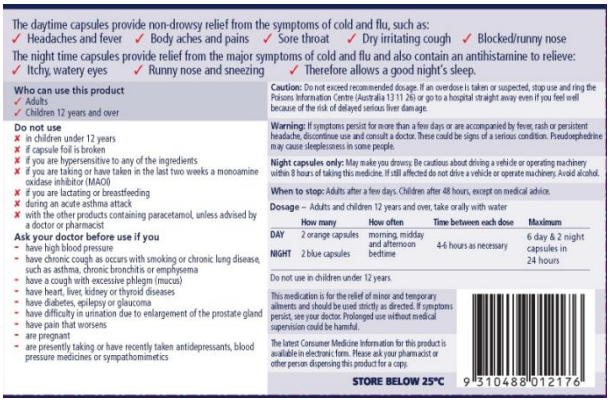
Graphic 16 Options for consumer friendly language

Current consumer information panel

Proposed Medicine Information Box with brand contrasting colours

Graphic 17 Options for visual cues

Current consumer information panel



The daytime capsules provide non-drowsy relief from the symptoms of cold and flu, such as:
✓ Headaches and fever ✓ Body aches and pains ✓ Sore throat ✓ Dry irritating cough ✓ Blocked/runny nose
The night time capsules provide relief from the major symptoms of cold and flu and also contain an antihistamine to relieve:
✓ Itchy, watery eyes ✓ Runny nose and sneezing ✓ Therefore allows a good night's sleep.

Who can use this product
✓ Adults
✓ Children 12 years and over

Do not use
✘ in children under 12 years
✘ if capsule foil is broken
✘ if you are hypersensitive to any of the ingredients
✘ if you are taking or have taken in the last two weeks a monoamine oxidase inhibitor (MAOI)
✘ if you are lactating or breastfeeding
✘ during an acute asthma attack
✘ with the other products containing paracetamol, unless advised by a doctor or pharmacist

Ask your doctor before use if you
- have high blood pressure
- have chronic cough as occurs with smoking or chronic lung disease, such as asthma, chronic bronchitis or emphysema
- have a cough with excessive phlegm (mucus)
- have heart, liver, kidney or thyroid diseases
- have diabetes, epilepsy or glaucoma
- have difficulty in urination due to enlargement of the prostate gland
- have pain that worsens
- are pregnant
- are presently taking or have recently taken antidepressants, blood pressure medicines or sympathomimetics

Caution: Do not exceed recommended dosage. If an overdose is taken or suspected, stop use and ring the Poisons Information Centre (Australia 13 11 26) or go to a hospital straight away even if you feel well because of the risk of delayed serious liver damage.

Warning: If symptoms persist for more than a few days or are accompanied by fever, rash or persistent headache, discontinue use and consult a doctor. These could be signs of a serious condition. Pseudoephedrine may cause sleeplessness in some people.

Night capsules only: May make you drowsy. Be cautious about driving a vehicle or operating machinery within 8 hours of taking this medicine. If still affected do not drive a vehicle or operate machinery. Avoid alcohol.

When to stop: Adults after a few days. Children after 48 hours, except on medical advice.

Dosage – Adults and children 12 years and over, take orally with water

	How many	How often	Time between each dose	Maximum
DAY	2 orange capsules	morning, midday and afternoon	4-6 hours as necessary	6 day & 2 night capsules in 24 hours
NIGHT	2 blue capsules	bedtime		

Do not use in children under 12 years.

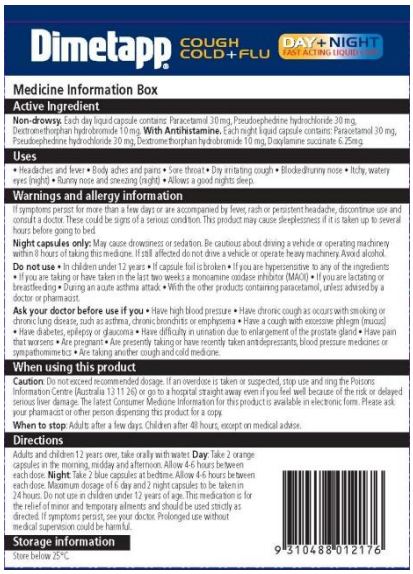
This medication is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist, see your doctor. Prolonged use without medical supervision could be harmful.

The latest Consumer Medicine Information for this product is available in electronic form. Please ask your pharmacist or other person dispensing this product for a copy.

STORE BELOW 25°C

9 310488 012176

Proposed Medicine Information Box
with brand and colours



Dimetapp COUGH COLD+FLU DAY+NIGHT FAST ACTING LIQUID

Medicine Information Box

Active Ingredient

Non-drowsy. Each day liquid capsule contains: Paracetamol 30 mg, Pseudoephedrine hydrochloride 30 mg, Dextromethorphan hydrobromide 10 mg. **With Antihistamine.** Each night liquid capsule contains: Paracetamol 30 mg, Pseudoephedrine hydrochloride 30 mg, Dextromethorphan hydrobromide 10 mg, Doxylamine succinate 6.25mg.

Uses

• Headaches and fever • Body aches and pains • Sore throat • Dry irritating cough • Blocked/runny nose • Itchy, watery eyes (night) • Runny nose and sneezing (night) • Allows a good nights sleep.

Warnings and allergy information

If symptoms persist for more than a few days or are accompanied by fever, rash or persistent headache, discontinue use and consult a doctor. These could be signs of a serious condition. This product may cause sleeplessness if it is taken up to several hours before going to bed.

Night capsules only: May cause drowsiness or sedation. Be cautious about driving a vehicle or operating machinery within 8 hours of taking this medicine. If still affected do not drive a vehicle or operate heavy machinery. Avoid alcohol.

Do not use • In children under 12 years • If capsule foil is broken • If you are hypersensitive to any of the ingredients • If you are taking or have taken in the last two weeks a monoamine oxidase inhibitor (MAOI) • If you are lactating or breastfeeding • During an acute asthma attack • With the other products containing paracetamol, unless advised by a doctor or pharmacist.

Ask your doctor before use if you • Have high blood pressure • Have chronic cough as occurs with smoking or chronic lung disease, such as asthma, chronic bronchitis or emphysema • Have a cough with excessive phlegm (mucus) • Have diabetes, epilepsy or glaucoma • Have difficulty in urination due to enlargement of the prostate gland • Have pain that worsens • Are pregnant • Are presently taking or have recently taken antidepressants, blood pressure medicines or sympathomimetics • Are taking another cough and cold medicine.

When using this product

Caution: Do not exceed recommended dosage. If an overdose is taken or suspected, stop use and ring the Poisons Information Centre (Australia 13 11 26) or go to a hospital straight away even if you feel well because of the risk of delayed serious liver damage. The latest Consumer Medicine Information for this product is available in electronic form. Please ask your pharmacist or other person dispensing this product for a copy.

When to stop: Adults after a few days. Children after 48 hours, except on medical advice.

Directions

Adults and children 12 years over, take orally with water. **Day:** Take 2 orange capsules in the morning, midday and afternoon. Allow 4-6 hours between each dose. **Night:** Take 2 blue capsules at bedtime. Allow 4-6 hours between each dose. Maximum dosage of 6 day and 2 night capsules to be taken in 24 hours. Do not use in children under 12 years of age. This medication is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist, see your doctor. Prolonged use without medical supervision could be harmful.

Storage information

Store below 25°C.

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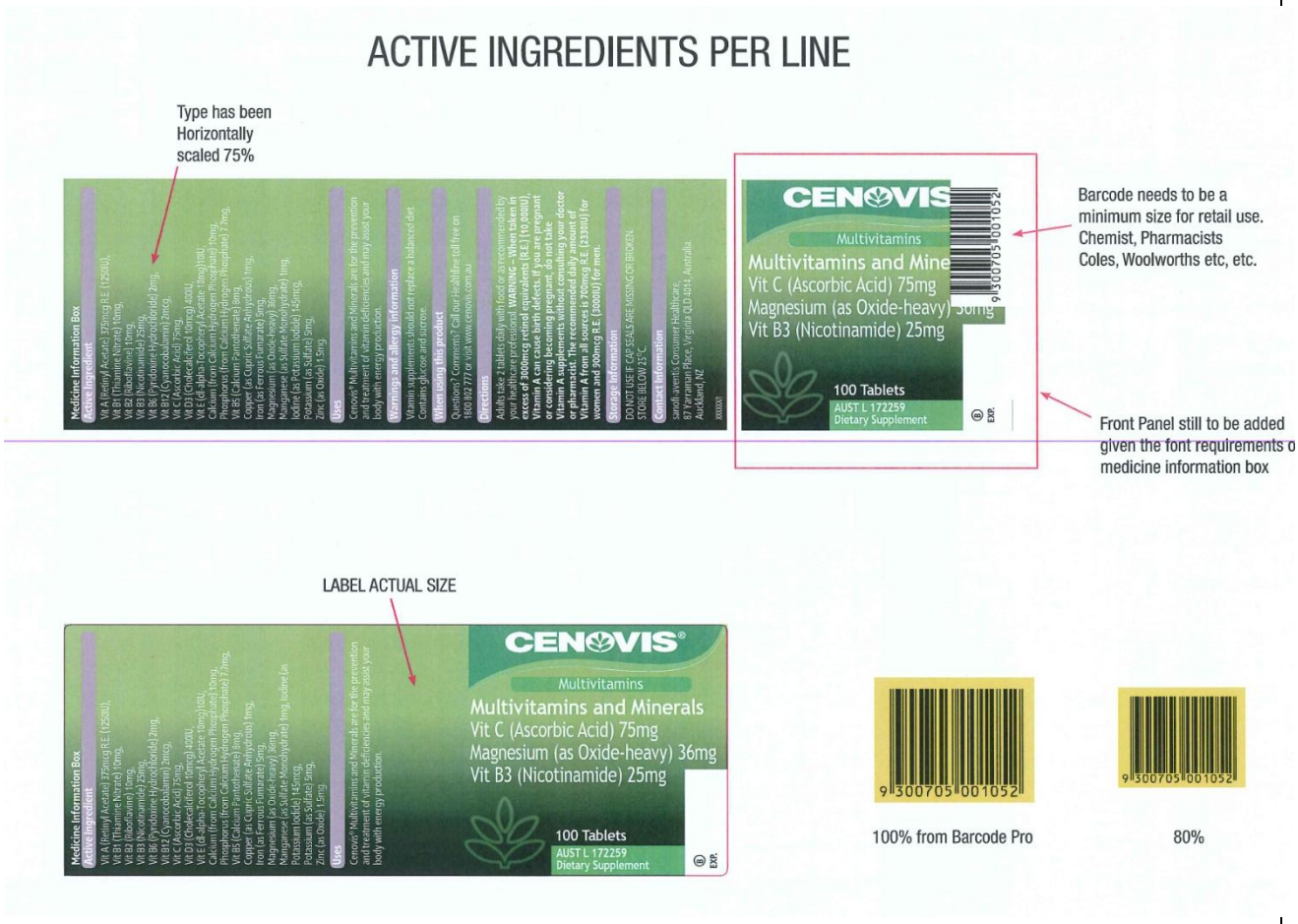
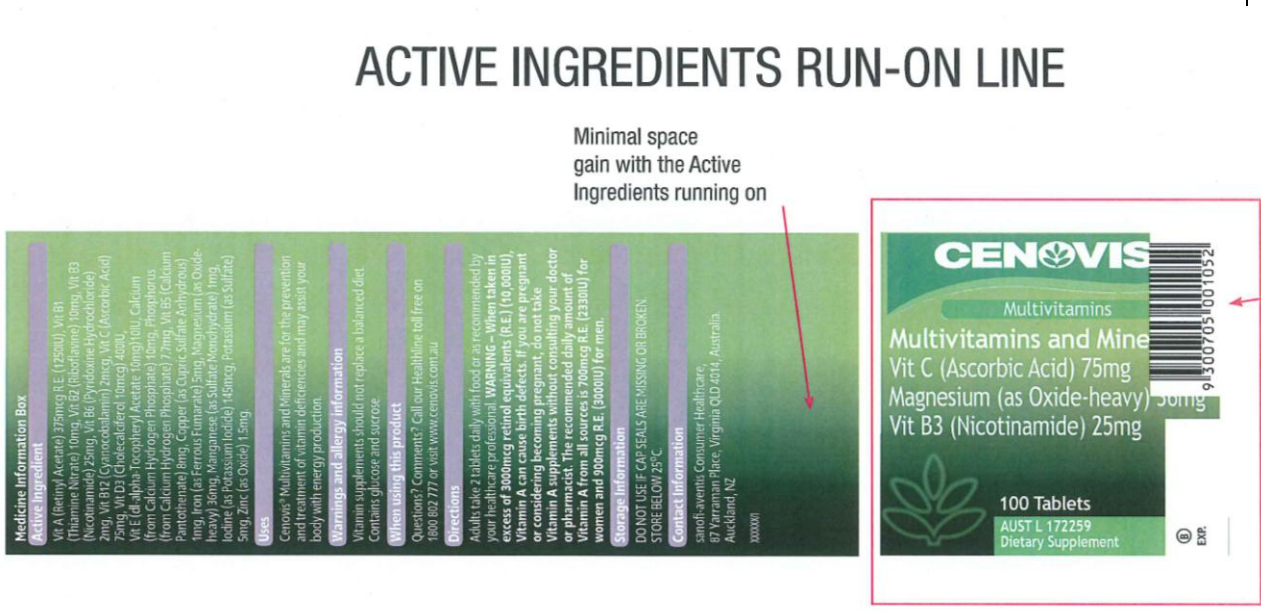
Graphic 18 Issues for Bottle Labels particularly Multi-ingredient medicines





Graphic 18 Continued from previous page

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- Further work needs to be done in the development of a format that consumers can understand. ASMI members have learned a lot through using the Code of Practice for labelling of non-prescription medicines and consumer testing and these advances should not be lost. ASMI agrees with the proposal in principle, but format, layout, titles and order of information MUST be consumer tested prior to adoption. The TGA should, however, consider introducing some flexibility into the standard to accommodate different product types, categories and pack sizes. For example a matrix of appropriate mandatory headings for different product types.
- The TGA could remove the requirement to include the title "Medicine Information Box" (the title does not appear to add anything as the grouping of the information appears to be self-explanatory).
- The TGA could consider the use of bullet points and visual cues for warnings and precautions (e.g. ticks, crosses and question marks).
- The TGA should consider deleting the "Storage Information" title.
- The TGA should consider using more consumer friendly titles, such as 'When not to use', rather than 'Uses' and allow bolding or boxing of headings.
- The TGA could allow branding or the use of colour on the panel to improve contrast and readability.
- The TGA could consider a matrixing approach to headings (outlining which ones are required for which categories) so that there will be a graded approach for toothpastes, sunscreens, complementary medicines and OTC medicines (this could also allow tailoring to accommodate different dosage forms and pack sizes). The TGA should consider the possibility of using a different back-of-pack altogether if that can be justified.
- The TGA should consider exempting small containers from the "Medicine Information Box" format requirements rather than require exemption justifications for each case.

Caveats

The figures in throughout the Consultation paper are flawed and have hampered the consultation process (for a full discussion see Appendices 1 and 2). As discussed above, some apparent changes have not been discussed in the Consultation paper and other proposed changes are unclear or contradictory. It has therefore been difficult to clearly identify the scope of the Consultation paper. Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

Dispensing label space

Summary of ASMI Position

This item has been identified as applying to prescription medicines only.

ASMI therefore has no comment to make in relation to this part of the Consultation paper.

Blister strip labelling

Stated Objective(s)

The consultation paper states that the objective of the Review is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issue:

- Information about the active ingredient(s) contained in the medicine and instructions for usage are not available on the blister strip.

Consumer risk(s) identified in the consultation paper

The Consultation paper indicates that: "*Often blister strips are stored away from their outer wrapping or packaging that contains the information about how to use the medicine safely. For example, it is not uncommon for people to carry a blister strip in their handbag, purse or travel bags without the primary container.*"

The Consultation paper further indicates that: *"There is a risk that the medicine may not be taken in accordance with the dosage instructions or it may be taken with another medicine that contains the same active ingredient".*

Summary of ASMI Position

- ASMI rejects the proposal to include the batch and expiry data more frequently on the blister strip than currently required for the following reasons:
    - TGO 69 already requires the brand name, active ingredient and amount of active ingredient to be on the blister and companies comply with this requirement by reproducing this information in relation to every 2 dosage units regardless of the ability to segment
    - The identified risk is that blister strips stored away from the packaging will not contain information about how to use the medicine safely. However, the proposed repetition of the batch and expiry data will not provide this information and will therefore have no impact on the quality use of medicine.
    - The proposed change does nothing to address the identified risk and therefore cannot be justified.
    - More frequent inclusion of the batch and expiry data on the blister strips will have far-reaching consequences throughout the manufacturing and supply chain and will result in substantial increases in costs. These issues are presented in depth in Appendix 6.
- The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements.
- The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.
- The proposal will result in a substantial increase in costs, with no clear benefit to consumers.

Notes on the Evidence Provided by the TGA

In support of the statements made about consumer risks and in support of the proposed regulatory changes, the TGA has provided no references.

Proposed regulatory change(s) and ASMI concerns with the proposals

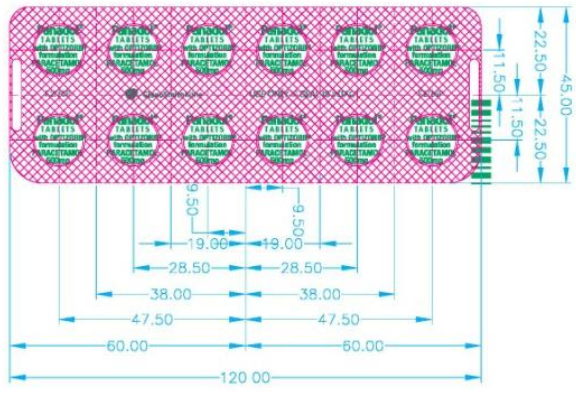
Proposed Regulatory Change	Concerns
For blister strips, other than those that have a "race track" blister strip format to facilitate the quality use of the medicine (such as oral contraceptives), the following requirements are proposed: 6.1 The brand name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date must be repeated at least once every two units. 6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment. 6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines. 6.4 Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil. For oral contraceptives and other medicines that have a "race track" format to support their safe use, the TGA proposes the following requirement: 6.5 Blister strips that have a "race track format" must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.	• The stated intention of the proposals is to reduce the risk associated with separated doses not including essential information. • The TGA has not provided any evidence as to how widespread the practice of storing blisters separate from their non-prescription cartons is (only to say that it is "often"). • It is unclear what the TGA's precise intention is in relation to change 6.2. The requirement applies to blister strips that "can be segmented" rather than to blister strips "designed to be segmented". The requirement therefore could apply to all blisters that can be cut. • Sponsors only have two options to meet the proposed change; (1) to pre-print batch sized quantities of foil with the anticipated batch and expiry data; (2) to post-print the foil at the time of manufacture. • Both of these options will be associated with increased costs and both carry with them significant issues in relation to manufacturing practicalities. These issues are presented in depth in Appendix 6 • These options are also impractical from a global sourcing perspective. Overseas manufacturers are unlikely to adopt such expensive and complicated arrangements for Australian product only. The natural consequences will be increased prices or discontinuations.

Proposed Regulatory Change	Concerns
	• It is also possible that these extra costs may see changes away from blisters to other packaging forms such as bottles. • To accommodate the additional batch/expiry information, the size of the blister will need to change and this will impact overall packaging dimensions and have flow-on effects through the supply chain. • ASMI further notes that figure 10 (which purports to show compliance with the proposed changes) shows a perforation which will separate every piece of required information into two incomplete parts. <u>This figure cannot represent the proposed changes.</u>

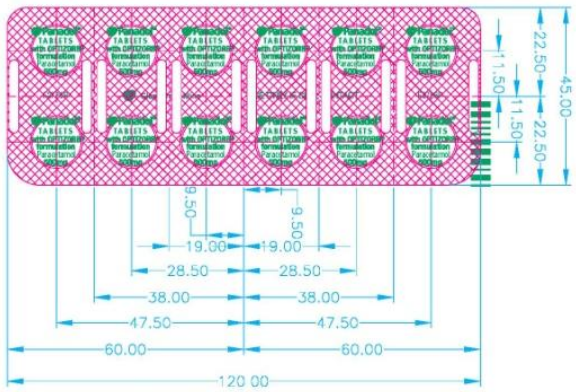
<u>EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW</u>

Graphic 19 Issues with Proposal 6.1 Incorporating Batch and Expiry Data every two dose units

White zones represent (B) and Exp coding areas. To achieve application of real time data printing every two dose units will require new equipment and larger blister platforms.



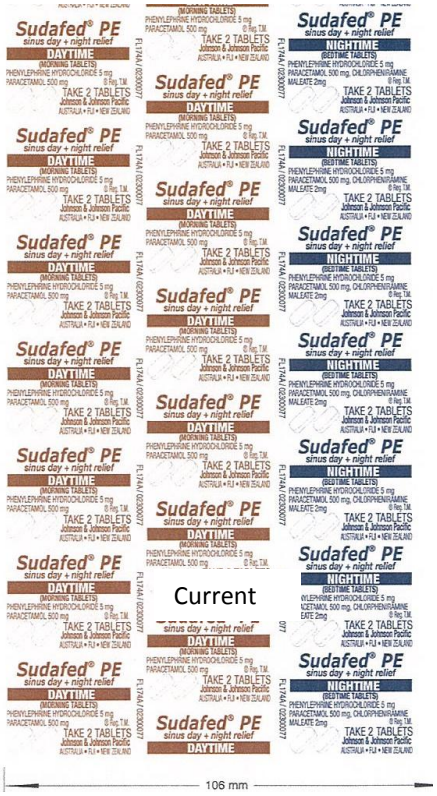
Current



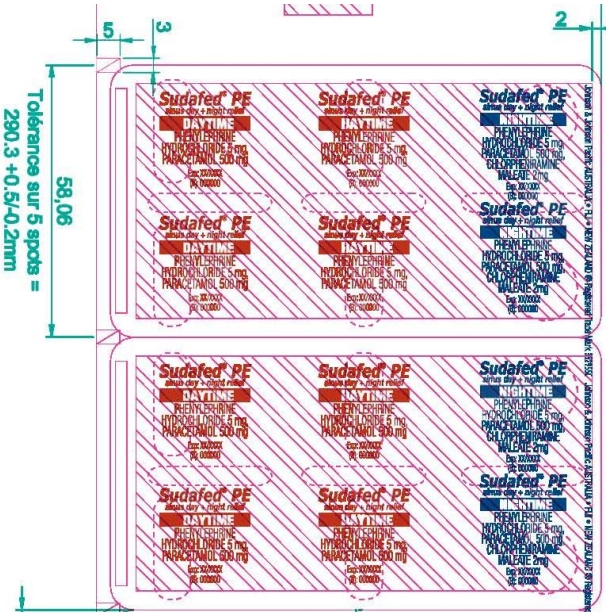
Proposed
No calculations of necessary blister platform size have been undertaken.

Graphic 20 Issues with Proposal 6.1 Day and Night Packs – Multiple colour print

Current Foil Artwork

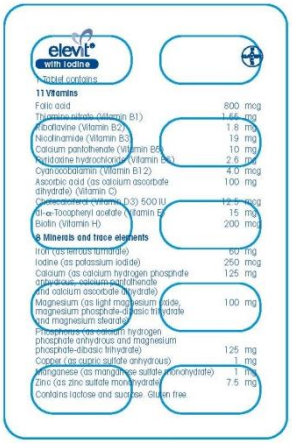


Concept for proposal



Graphic 21 Issues with Proposal 6.4 – More than 3 ingredients

Current



Proposal Concept

No calculations of necessary blister platform size have been undertaken.

Alternative options

Proposals:

- Non-regulatory approaches to mitigate risks must also be considered (e.g. consumer education on the risks of removing blisters from their packaging)
- Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- Any change to the blister printing requirements will result in enormous capital expenditure and increased product dimensions and associated increased costs and should only be proposed following a complete review of the regulation impacts.

Caveats

This section of the Consultation paper contains ambiguities which are not helped by the error in the accompanying figure. Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

Small containers

Stated Objective(s)

It is unclear what the objective of this section of the Consultation paper is.

Consumer risk(s) identified in the consultation paper

The Consultation paper acknowledges the limitations imposed on amount of information that can be included on the label of a small container and concludes that: "*It is therefore critical that the small container contains the most important information that a consumer or health care practitioner needs*".

Summary of ASMI Position

- It appears that the proposed changes simply re-state the current arrangements.
- The TGA should clarify exactly how the proposed changes differ from the current arrangements.
- ASMI agrees with the comments about the practical considerations and challenges in relation to small containers.
- The TGA should consider exempting small containers from the "Prominence of Active" and the "Medicine Information Box" format requirements rather than require exemption justifications for each case.
- In the absence of evidence demonstrating that current labelling requirements for non-prescription medicines pose a risk to consumers, the current labelling requirements should remain.

Notes on the Evidence Provided by the TGA

In support of the statements made about consumer risks and in support of the proposed regulatory changes, the TGA has provided no references.

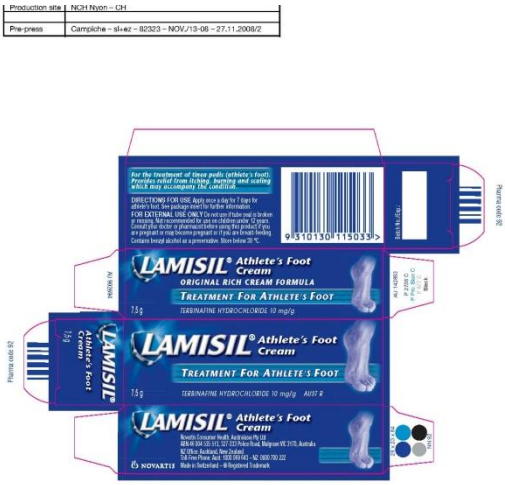
Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	**Concerns**
[for medicine containers with a nominal capacity of 20 millilitres or less]: 7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use. 7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres:	• It is unclear what the intent of the proposal actually is. What is proposed for the label is not significantly different to TGO 69 requirements. However, when taken in context of the Medicine Information Box proposal, the impact on small containers is significant. Proposal 7.1 also requires a primary pack that fully complies with all labelling requirements AND a pack

Proposed Regulatory Change	Concerns
• The brand name of the medicine • The name(s) of all active ingredients in the medicine • For ophthalmic preparations the name of any antimicrobial preservatives in the medicine • Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert • The batch number of the medicine • The expiry date of the medicine • If an injection, the approved route of administration • If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened • If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened 7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.	insert with detailed instructions for use. • It is unnecessary and wasteful to require a pack insert as well as a fully compliant primary pack • The Medicine Information Box format is difficult, if not impossible for small containers. • The alternative to achieving a Medicine Information Box on small packs is to abandon the boxed formatting or to increase the size of the container. The second option is costly requiring not only larger packaging but new stability testing and increased costs through the whole supply chain. It may also raise deceptive packaging concerns and consumer complaints. • Inclusion of a pack insert will increase costs. • Concertina/peel back/roll out labels are costly. There are likely to be issues as consumers do not always recognise the feature. Also, if opened in store, they may be assumed to have been tampered with or damaged. • Provide clarification that space for dispensing sticker is for prescription medicines only. • It is noted that individually wrapped goods have not been addressed in the consultation, i.e. is it out of scope or has it been omitted unintentionally?

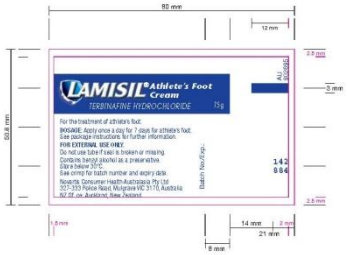
EXAMPLES OF ARTWORK WHICH DEMONSTRATE THESE ISSUES ARE INCLUDED BELOW

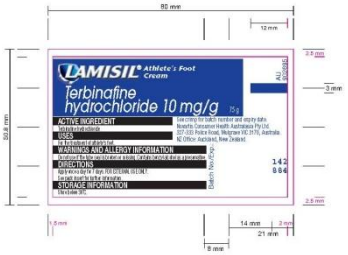
Graphic 22 Issues with Proposals of the labelling review for small packs



Current

Overall impact of proposals





Tube Artwork

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- Given the practical limitations of small containers, the impact of the proposed changes in their entirety need to be examined in detail (for example the inclusion for the "Medicines Information Box" headings alone will have a significant impact).
- The TGA should consider exempting small packs from the "Prominence of Active" and the "Medicine Information Box" requirements (as part of a tailored approach to the Medicine Information Box for different categories, pack formats and dosage forms).
- The TGA should consider treating individually wrapped goods as per blister packs.
- The TGA should consider the impact on other formats such as roll wraps (where a cut-off based on container volume is not appropriate).

Caveats

It appears that the proposed regulatory changes simply re-state the current arrangements. To the extent that this is not the case, the TGA need to provide clarity as to what, exactly, is changing. Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

Pack Inserts

Stated Objective(s)

It is unclear what the objective of this section of the Consultation paper is.

Consumer risk(s) identified in the consultation paper

The Consultation paper suggests that "*If pack inserts are used to compensate for information restrictions on small containers, it is important that the insert is concise and does not include extraneous information, such as advertising material*".

Summary of ASMI Position

- It appears that the proposed changes simply re-state the current arrangements.
- The TGA should clarify exactly how the proposed changes differ from the current arrangements.

Notes on the Evidence Provided by the TGA

In support of the statements made about consumer risks and in support of the proposed regulatory changes, the TGA has provided no references.

Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	**Concerns**
8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.	• The TGA needs to clarify what is meant by "advertising material", as advertising and promotional material per se are currently not allowed in labelling. • It should be noted that ARGOM does allow cross-referencing to: o more suitable dosage forms within the same range for different age groups, e.g. liquids instead of a solid dose form for children o another product that can be used in conjunction with the current product as part of the treatment

Proposed Regulatory Change	Concerns
	regimen ○ a sponsor's other products within the same product range that have the same trade name as the current product, e.g. nicotine replacement therapy dose forms • ASMI supports the continuing ability for sponsors to appropriately cross-reference other (possibly more suitable) products. • ASMI questions whether this proposal is designed to restrict referral to patient support programs which aim to aid consumer compliance. ASMI requests that the TGA provide clarity on this point.
8.2 A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.	• ASMI understands that this represents the current requirements. However, the TGA should clarify why such an arrangement is entirely unsuitable (for example including this information on the inside of the carton of a single use product may be acceptable and would minimise the amount of materials used).

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

- That pack inserts should only be required if all the necessary information cannot be included on the product's label.
- ASMI suggests that the ARGOM already provides appropriate guidelines in relation to cross-referencing of other products and these should remain in place.

Caveats

It appears that the proposed regulatory changes simply re-state the current arrangements. To the extent that this is not the case, the TGA need to provide clarity as to what, exactly, is changing. Where stakeholders have misinterpreted the proposed changes we suggest that a further round of consultations will be necessary.

Labels and packaging advisory committee

Stated Objective(s)

The consultation paper states that the objective of this part of the review is to address the fact that:

- The TGA does not currently have access to specific expertise relating to the quality use of medicines for labelling and packaging.

Consumer risk(s) identified in the consultation paper

None identified.

Summary of ASMI Position

- ASMI appreciates the value of an appropriately constituted Committee in objectively applying clear guidelines and protocols to expedite evidence-based decision making in relation to medicines labelling and packaging.

Proposed regulatory change(s) and ASMI concerns with the proposals

Proposed Regulatory Change	Concerns
The TGA proposes to establish a panel to provide advice on the acceptability of proposed names, labels and packaging, particularly for products involving potential umbrella branding or look-alike sound-alike issues. It is proposed that this expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to medicine labels and packaging.	• Industry would like clear guidelines and protocols developed as a starting point. The guidelines and protocols should allow objective assessment of the risks, benefits and merits of labelling and packaging. • A Committee such as the one proposed should only be established if stakeholders agree that the proper functioning of the guidelines and protocols would be enhanced by the Committee. • Labelling decisions (whether made by the Committee or by the TGA) need to be objective and consistently applied. • The composition of the committee should include acknowledged experts in the field of manufacturing, packaging, printing, and communication. • Uncertainty exists as to how the Committee decisions would fit into the evaluation process and what effect such decisions

Proposed Regulatory Change	Concerns
	would have on predictable timeframes. • Sponsors want to be confident of the success of a product name at the start of the product development phase and this is why clear guidelines and protocols will be essential. To find out at the end of an evaluation process that a branding proposition is unsuccessful is a costly exercise. • Sponsors need to be confident that investment in developing and testing labelling to an agreed set of guidelines and protocols, will result in an application that will be accepted by the TGA. • Clarity is required as to the exact composition of the proposed Committee, its role, the nature of its decisions, whether those decisions are binding or contestable.

Alternative options

ASMI suggests that clear guidelines and protocols in relation to medicines labelling be developed as a starting point and that the Committee only be established if stakeholders agree that the guidelines and protocols require such additional support (e.g. because the guidelines fail to deliver predictable outcomes).

Caveats

Without knowing the precise role and composition of the proposed Committee ASMI is unable to appropriately assess the merits of the proposed Committee.